Measuring Quality in Pediatric Endoscopy: Are we there yet?

Jenifer R. Lightdale, MD, MPH, FAAP
Division Chief, Gastroenterology
Chief Quality Officer
UMass Memorial
Children’s Medical Center
Professor of Pediatrics
University of Massachusetts

Faculty Disclosures
– Mead-Johnson (Speaker Honorarium)
– Perrigo (Medical Advisory Board)
– Norgine (Consulting)
– ASGE (Editorial Honorarium)

Gastrointestinal Endoscopy
• Fundamental to the practice of pediatric gastroenterology
• Tremendous and proven value
  — Diagnosis
  — Treatment

Gastrointestinal Endoscopy
• Benefits are maximized if and when:
  — Quality of procedure is assured
  — Performed optimally
• Requires consensus around definitions
  — “Quality”
  — “Optimal”
• Involves metrics
  — Accurate
  — Meaningful
  — Practical

What is endoscopic quality?
• Difficult to measure unless it can be
  — Recognized
  — Defined
• Very likely it should assure society at large
  — Recommended and performed when appropriate (indicated)
  — Performed expeditiously, skillfully, successfully, safely and comfortably
  — High value (best quality for least cost)

IOM’s 6 Domains of Quality
• Effective
• Patient-centered
• Safe
• Efficient
• Timely
• Equitable

Bjorkman, 2006; Rex, 2006; Cotton, 2006; Lieberman, 2007
Donabedien, JAMA, 1988; Blumenthal, NEJM, 1996; IOM, 2001
Elements of Endoscopic Quality

• Indicated
• Well prepared (informed) patients
• Minimizes risk
• Sedation plan
• Correct equipment
• Procedurally complete
• Reasonable duration
• Diagnostic
• Identifies abnormalities
• Appropriate tissue sampling

• Therapeutic (as appropriate)
• Maintains safety
• Ensures recovery
• Communication re: follow-up
• Pathology
• Accurate documentation/billing
• High value
• Positive patient feedback (satisfaction)

GiECAT_KIDS

• Gastrointestinal Endoscopy Competency Assessment Tool for pediatric colonoscopy (GiECAT_KIDS)
• Catharine M. Walsh, MD, PhEd
• Developed via Delphi method
  – >40 pediatric gastroenterologists from across North America
  – Heterogeneous group with broad expertise
  – 5 rounds of surveys (~76% participants all 5!)
• 3 main competency domains of colonoscopy in children
  – Technical (psychomotor skill)
  – Cognitive (knowledge)
  – Integrative (judgment, clinical reasoning)

Validation of GiECAT_KIDS

<table>
<thead>
<tr>
<th>Demographic Characteristics</th>
<th>Training Level</th>
<th>Hand dominance</th>
<th>Sex</th>
<th>Number of Years Performing Colonoscopy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>GI Fellow</td>
<td>GI Attending</td>
<td>Male</td>
<td>Female</td>
</tr>
<tr>
<td>Overall</td>
<td>33 (10)</td>
<td>33 (10)</td>
<td>40</td>
<td>30</td>
</tr>
<tr>
<td>Novice (25)</td>
<td>100.0 (9)</td>
<td>100.0 (9)</td>
<td>90</td>
<td>10</td>
</tr>
<tr>
<td>Intermediate (21)</td>
<td>100.0 (9)</td>
<td>100.0 (9)</td>
<td>90</td>
<td>10</td>
</tr>
<tr>
<td>Advanced (19)</td>
<td>100.0 (10)</td>
<td>100.0 (10)</td>
<td>90</td>
<td>10</td>
</tr>
</tbody>
</table>

GiECAT_KIDS Score

• 18-item highly structured checklist (CL)
  – Outlines key steps required to complete the procedure
  – Modeled after validated CLs used in General Surgery
  – Scored dichotomously (1 = done correctly or 0 = not done/done incorrectly)
  – Potential range of scores 0-18
• 7 domain Global Rating Scale (GRS)
  – Assesses holistic aspects of skill in terms of autonomy
  – Scored on a 5-point Likert scale
  – Higher scores reflective of better performance (more autonomy demonstrated) by the endoscopist
  – Potential range of scores 7-35

GiECAT_KIDS GRS Likert Scale

<table>
<thead>
<tr>
<th>Global Rating Item</th>
<th>Definition</th>
<th>Competency Domain</th>
<th>Mean ± Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Pre-travel/End of Procedure</td>
<td>Components of procedure that involve precursor steps and preparatory measures (eg: patient preparation, sedation, equipment selection and setup)</td>
<td>Technical</td>
<td>8.2 ± 1.3</td>
</tr>
<tr>
<td>2. Visualization of Abnormalities</td>
<td>Components of ability to view a normal vs abnormal condition</td>
<td>Technical</td>
<td>8.4 ± 0.9</td>
</tr>
<tr>
<td>3. Visualization of Normality</td>
<td>Components of ability to view a normal vs abnormal condition</td>
<td>Technical</td>
<td>8.6 ± 0.9</td>
</tr>
<tr>
<td>4. Knowledge of Pharmacology</td>
<td>Components of ability to understand the indications, contraindications, and potential complications of the procedure</td>
<td>Technical</td>
<td>8.8 ± 0.9</td>
</tr>
<tr>
<td>5. Complications and Management of Grafts</td>
<td>Components of ability to understand the indications, contraindications, and potential complications of the procedure</td>
<td>Technical</td>
<td>8.9 ± 0.9</td>
</tr>
<tr>
<td>6. Follow-up</td>
<td>Components of ability to understand the indications, contraindications, and potential complications of the procedure</td>
<td>Technical</td>
<td>9.0 ± 0.9</td>
</tr>
</tbody>
</table>

GiECAT_KIDS Global Rating Scale

Walsh, GIE, 2014; Walsh, 2014, JPGN; Walsh, JPGN, in press (2014)
GiECAT-KIDS Checklist Items
(1=Y, 0=not done/N)

- Pre-procedure
  - Technical (1)
    - i.e. Item 5: Checks that equipment is functioning
  - Cognitive (n=3)
    - i.e. Item 1: Reviews and obtains patient history
  - Integrative (2)
    - i.e. Item 2: Takes action in response (i.e. SBE prophylaxis)
- Procedure
  - Technical (6); Cognitive (3); Integrative (3)
- Post-procedure
  - Integrative (2)
    - i.e. Item 18: Education patient/caregivers about findings and makes follow-up plan

Reliability of GiECAT-KIDS
(Each Component and Total Score)

- Inter-item
  - Each Component and Total Score
    - ICC, single measure
    - ICC, average measure

Validity of GiECAT-KIDS
(Each component and Total Score)

- Distinguishes novices vs. intermed vs. advanced

<table>
<thead>
<tr>
<th>Component of GiECAT-KIDS Scale</th>
<th>Novice</th>
<th>Intermediate</th>
<th>Advanced</th>
<th>p Value*</th>
<th>Maximum possible score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total GiECAT score*</td>
<td>22.00</td>
<td>10.50</td>
<td>51.00 [3.25]</td>
<td>&lt; 0.001</td>
<td>53</td>
</tr>
<tr>
<td>Global Rating Scale score**</td>
<td>14.00</td>
<td>7.00</td>
<td>34.00 [1.00]</td>
<td>&lt; 0.001</td>
<td>35</td>
</tr>
<tr>
<td>Checklist score*</td>
<td>9.00</td>
<td>5.00</td>
<td>17.00 [1.00]</td>
<td>&lt; 0.001</td>
<td>18</td>
</tr>
</tbody>
</table>

- Concurrent validity (p<.001 for each)

<table>
<thead>
<tr>
<th>Component of GiECAT-KIDS Scale</th>
<th>Number of previous colonoscopies</th>
<th>Oral induction rate</th>
<th>Terminal ileal intubation rate</th>
<th>Physician global assessment of skill</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total GiECAT score</td>
<td>0.91</td>
<td>0.52</td>
<td>0.62</td>
<td>0.95</td>
</tr>
<tr>
<td>Global Rating Scale score</td>
<td>0.92</td>
<td>0.65</td>
<td>0.80</td>
<td>0.94</td>
</tr>
<tr>
<td>Checklist score</td>
<td>0.84</td>
<td>0.79</td>
<td>0.86</td>
<td>0.89</td>
</tr>
</tbody>
</table>

GiECAT-KIDS Summary To Date

- Rigorously developed metric of colonoscopy in the context of pediatric care
  - By and for MDs trained to be pediatric endoscopists
  - In children who require colonoscopy
- Rigorously validated (reliability, validity)
- Ready for “prime-time”
  - Training programs...!
  - Credentialing...?
Other Quality Metrics for Pediatric Endoscopy

- NASPGHAN MOC Part IV “IQ=E” modules
  - Endoscopy Quality (25 points)
  - Colonoscopy Quality (25 points)
  - Informed Consent (25 points)
- Referenced
- Less well validated
- Practical
- Process oriented
- Involve universally important outcomes
- Can be tracked by reviewing documentation

Quality of Endoscopy Documentation

- Data shows tremendous variation in reporting among endoscopists
  - 438,000 procedures (2004-2006) from the Clinical Outcomes Research Initiative (CORI) *
- Data from pediatrics shows same pattern!
  - 21,800 pediatric procedures from Peds-CORI network:**
  - Similar variation in documentation

*Lieberman, 2009; **Thakkar, 2013
IOM’s 6 Domains of Quality

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IQ=E and Measuring Quality

• 225 participants
  – Most of whom have completed at least the first of three required data entry steps
• Upper Endoscopy Module
  – N=81
• Colonoscopy Module
  – N=58

MOC Upper Endoscopy – Data Entry Period 1

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Average compliance with procedural documentation requirements</td>
<td>84.2%</td>
</tr>
<tr>
<td>2. Average % of procedure reports shared with PCP or referring</td>
<td>63.8%</td>
</tr>
<tr>
<td>3. Average % documentation of discussion of biopsy results with</td>
<td>90.4%</td>
</tr>
<tr>
<td>4. Average time frame for results to be reported to the patient/</td>
<td>8.0 days</td>
</tr>
<tr>
<td>5. Average % upper endoscopies performed that resulted in change</td>
<td>59.6%</td>
</tr>
</tbody>
</table>

Colonoscopy – Data Entry 1

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Average compliance with documentation requirements across</td>
<td>91.3%</td>
</tr>
<tr>
<td>2. Average total colonoscopy time</td>
<td>35.7 minutes</td>
</tr>
<tr>
<td>3. Average total time to the cecum</td>
<td>20.9 minutes</td>
</tr>
<tr>
<td>4. Average % successful terminal ileum intubation among cases in</td>
<td>91.8%</td>
</tr>
<tr>
<td>5. Average % colonoscopies performed that resulted in change in</td>
<td>68.0%</td>
</tr>
</tbody>
</table>

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Safety of Endoscopy in Children

• Pediatric endoscopy is inherently risky...
• Adverse events are rare
• Tracking AEs at the provider or institutional levels may not provide a meaningful measure of quality

• Peds-CORI data from >10,000 procedures*
  – Overall rate of complications 2.3%
  – Risks of hypoxia from sedation related events most common 1.5%
  – Risk of bleeding 0.3%

*Thakkar, 2007

Tracking Complications

• Requires standardized definitions*
  – “Complications”
  – “Adverse events”
  – i.e. How much bleeding is an AE?
• Feasible
• Institutionally required
• Methodologies
  – Not standardized
  – Vary by institution

*Jacobson, GIE, 2011

Safety of Endoscopy in Children

• Characteristics of patients most at risk for complications during pediatric EGD*
  – Younger age
  – Higher ASA class
• Presence of a trainee may be more associated with complications*
• Performance of therapeutic manoeuvres

*Thakkar, 2007

Tracking Complications

• BCH (ProVation Database)
  – Overall complication rate of 0.437%
• Possible to statistically estimate a crude and adjusted rate per 10,000 procedures/provider
  – Patient ASA status (complexity)
  – Procedure type (diagnostic vs. advanced)
• Funnel plot methodology
  – Upper control limit
  – Assumes common cause variation
  – Can be used to identify “special cause variation”

Complication Rates (Crude vs Adjusted)

Unpublished data; N=23,714 Complication Rate=38.8/10,000 procedures
### Tracking Complications – Next Steps

- Refining and standardizing definitions
  - Complications, Adverse events
- Reducing provider variability
  - Definitions
  - Thresholds to report
- Standardizing methodologies
- Refining measures – crude vs. adjusted
  - What factors are most important to consider?
  - i.e. ASA, patient age, weight, fellow presence?

### IOM’s 6 Domains of Quality

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### Measuring Efficiency and Value

- Increasing pressures to reduce costs of pediatric endoscopy
  - Proceduralist (me, you) is actually just a small part of costs
  - Anesthesia (OR time)
  - Pathology
- Reducing unnecessary and/or prolonged procedures may be very important
  - Exposure to anesthetics in children linked to neurotoxicity
  - PANDA U01 (Pediatric Anesthesia NeuroDevelopmental Assessment)*
  - “PACD” (Post-anesthesia cognitive dysfunction)

*Monteleone, 2014

### Measuring Efficiency and Value

- Appropriateness of procedure performance
  - Indications (Underuse vs. Overuse)
  - Duration (Too long vs. too short)
  - Technical Skill
  - Completeness
  - Tissue Sampling (Underuse vs. Overuse)

### Pediatric Endoscopy and Tissue Sampling

- Standard of care is to obtain biopsies in the absence of specific findings*
  - Different from adult endoscopy
- Risks of performing repeat endoscopy in pediatric populations
  - Considered to outweigh risks of obtaining biopsies
- Important to obtain biopsies *appropriately* when it is of value vs. Not to obtain them if unnecessary
  - May add cost

*Kori, 2002; Khakoo, 1999; Lightdale, 2013
Celiac Disease

- AGA recommends 4 to 6 proximal small bowel biopsies*
- May be additional value to bulb biopsies
  - Weir (2009)
  - Gastrointestinal Endoscopy (2010)
  - Gebrail (Abstract #174, NASPGHAN 2014)

Eosinophilic Esophagitis

- May be a patchy disease
- Requires biopsies for diagnosis
  - Pathologically defined by >15 Eos/HPF
- Increased sensitivity for diagnosis
  - 5 or more biopsies
  - Distal, mid, and proximal esophagus

Normal Appearing Colonic Mucosa

- Likely to be normal on pathological examination
  - Especially in the absence of diarrhea or elevated sedimentation rate
- Reducing the number of biopsies obtained from normal-appearing colons
  - May not significantly affect diagnostic yield
  - May lower healthcare costs
  - May improve efficiency
- Future studies are needed to determine best protocols for routine sampling during pediatric colonoscopy

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Are we there yet?

- Depends upon the question
- Are we ready to start measuring?
- Hell yeah!!!!
- Some metrics more validated than others

Measuring Quality in Pediatric Endoscopy

- Learned a lot from GiECATKIDS
  - Developing metrics
  - Validating them
- Should be employed by training programs
  - Provides standardized metrics
Are we there yet?

- GiECATKIDS also confirms pediatric colonoscopy differs from colonoscopy in adults
  - Patient preparation
  - Sedation
  - Frequency with which TI intubation is desirable
  - Spectrum of therapeutic manipulations
- Performance of colonoscopy in children requires
  - Pediatric-specific medical knowledge
  - Pediatric-specific technical competency
  - **Pediatric-specific quality metrics**

NASPGHAN MOC IQ=E

- Individual level
  - Offers ABP MOC credit
- Across NASPGHAN and greater field of pediatric endoscopy
  - May help to better establish and refine metrics
  - Comparators
  - Benchmarks

ACKNOWLEDGEMENTS

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THANK YOU!

REFERENCES